REMARKS

Reconsideration and allowance of this application are respectfully requested in light of the foregoing amendments and the following remarks.

Claim Status

Claims 1-12 and 14-18 are pending. No new matter was added.

§102/103 Claim Rejections

Claims 1-12 and 14-18 stand rejected under 35 U.S.C. §102(b) as being anticipated by or, in the alternative, under 35 U.S.C §103(a) as obvious over U.S. Patent No. 5,840,190 (hereinafter Scholander). Applicant traverses.

To anticipate a claim under 35 U.S.C. §102(b), a single source must contain all of the elements of the claim. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.,* 802 F.2d 1367, 1379, 231 USPQ 81, 90 (Fed. Cir. 1986); *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1574, 224 USPQ 409, 411 (Fed. Cir. 1984); *In re Marshall*, 578 F.2d 301, 304, 198 USPQ 344, 346 (C.C.P.A. 1978). Missing elements may not be supplied by the knowledge of one skilled in the art or the disclosure of another reference. *See Structural Rubber Prods. Co. v. Park Rubber Co.,* 749 F.2d 707, 716, 223 USPQ 1264, 1271 (Fed. Cir. 1984). Where a reference discloses less than all of the claimed elements, an Examiner may only rely on 35 U.S.C. §103. *See Titanium Metals Corp. v. Banner,* 778 F.2d 775, 780, 227 USPQ 773, 777 (Fed. Cir. 1985).

Looking to independent claim 1, the Examiner is of the opinion that in its abstract, column 3, line 66 to column 5, line 10, Scholander discloses a method for forming a membrane with at least one separating layer and a supporting layer comprising the steps:

a) preparation of a spinning solution comprising a membrane-forming polymer and a solvent system; (column 4, lines 38-50)

b) conversion of the spinning solution by means of a forming device into a shaped object with a first and a second surface; (column 4, lines 38-50)

c) bringing of the first and/or second surface into contact with a precipitant system comprising a polyelectrolyte wherein the polyelectrolyte is acrylic acid; (column 4, lines 51-66) and

d) washing and, if necessary, drying of the membrane. (Column 5, lines 8-10)

However, claim 1 of the present invention pertains to a method for production of an integrally asymmetric membrane with at least one separating layer and a supporting layer adjoining the separating layer. In order to obtain such a membrane, the process according to claim 1 of the present invention comprises a process step c), according to which the shaped object formed in process step b) is brought with its first and/or second surface into contact with a precipitant system, the properties of which are such that an integrally asymmetric membrane is formed which has a separating layer on that first and/or second surface which had been brought into contact with the precipitant system.

Moreover, the precipitant system of step c) comprises a polyelectrolyte with negative fixed charges, but no positive fixed charges. By adding the polyelectrolyte with negative fixed charges to the precipitant system, it had been found that the separation characteristics can be improved and, more importantly, a marked increase in separation efficiency is found. Looking to the first full paragraph on page 14 of the specification it states that,

> The membrane of the invention is characterised in that the polyelectrolyte with negative fixed charges in the separating layer or layers of the membrane is physically bound. This means that the said polyelectrolyte is not chemically bound in the separating layer of the membrane of the invention. The physical binding of the polyelectrolyte in the separating layer is so stable that neither washing, extraction and sterilisation, which are unavoidable during wet-chemical production of the membrane, nor the use of the membrane of the invention in separation media, such as the typical separation media for hemodialysis, leads to significant loss of polyelectrolyte from the membrane, or to a membrane with no polyelectrolyte content. A tentative explanation is that the polyelectrolyte is securely anchored in the separating layer of the membrane of the invention by interlocking and entanglement between the polymer chains of the polyelectrolyte and those of the membrane-forming polymer, as occurs, for example, during the method of the invention described above by bringing the solvent-moist shaped object formed in step b) into contact, in step c), with the polyelectrolyte-containing precipitant.

In contrast to claim 1 of the present invention, it is not possible to locate within Scholander a passage which discloses or makes obvious an integrally asymmetric membrane let along an integrally asymmetric membrane with at least one separating layer and a supporting layer adjoining the separating layer. This obviously includes the language within Scholander cited by the Examiner which includes:

- In the abstract, Scholander describes a "surface modified biocompatible membranes...and a method of preparing the membrane with functional

groups incorporated into the membrane materials to covalent bond compounds that infer biocompatibility to the surface."

- In column 3, line 66 to column 4, line 32, Scholander describes surface modified biocompatible membranes...and a method for preparing polymer surface modified biocompatible membranes with functional groups incorporated into the membrane material, thus to immobilize compounds that confer biocompatibility to the surface, where the incorporation of the surface modifying polymer takes place during formation of the membrane...achieved by

  Method A

  i) Preparation of a casting solution containing the membrane forming polymer.

  ii) Precipitating the membrane from the casting solution into a coagulation bath containing the surface modifying polymer, or

  Method B

  i) Preparation of a casting solution containing the membrane forming polymer and the surface modifying polymer.

  ii) Precipitating the membrane from the casting solution into a coagulation bath.

  Scholander's invention can be used on any polymeric material used for medical devices that are prepared by casting, spinning ...

- Looking now to column 4, line 38 to column 5, line 10, Scholander describes the preparation of a casting solution by dissolving 15-30% of the membrane

> forming polymer, to be chosen from cellulose ... polysulfone in dimethylacetamide, dimethylsulfoxide, acetone, dimethylformamide, formamide, organic or inorganic acids or mixtures thereof ... precipitating the membrane from the casting solution in a non-solvent, typically a hydrophilic solvent, preferably water, possibly with a small amount of added solvent for the membrane forming polymer ... and rinsing the precipitated, modified membrane carefully with water...

Thus, there is no explicit disclosure by Scholander of a process comprising a step in which the first and/or second surface of a shaped object is brought into contact with a precipitant system so that a membrane results, having a separating layer on that first and/or second surface that had been brought into contact with the precipitant system. Scholander also fails to disclose an integrally asymmetric membrane, let alone an integrally asymmetric membrane with at least one separating layer and a supporting layer adjoining the separating layer. Additionally, Scholander fails to disclose an integrally asymmetric membrane with at least one separating layer and a supporting layer adjoining the separating layer wherein the separating layer has physically bound therein a polyelectrolyte having negative fixed charges, but having no positive fixed charges and whereas the supporting structure is free from polyelectrolyte.

There is no implicit disclosure within Scholander that a membrane is formed having a separating layer on the first and/or second surface, as is alleged by the Examiner. Applicant must assume that because Scholander describes a process in

which a membrane is precipitated from a casting solution in a non-solvent (column 4, line 38 – column 5, line 10) the Examiner draws the conclusion (incorrectly) that an asymmetric membrane with a separating layer and a supporting layer is produced. The Examiner provides no further explanation.

Unfortunately for the Examiner, one skilled in the art would clearly know that this conclusion is not appropriate. Just because a precipitation is effected, one cannot conclude that inevitably an integrally asymmetric membrane with a separation layer is obtained. One skilled in the art knows that numerous factors during membrane production contribute to the end product achieved. Thus, depending on e.g. the polymer, the polymer concentration in the casting solution, the type of solvent system, the temperature of the casting solution, the precipitant system, the ratio of solvent to non-solvent in the precipitant system and the temperature of the precipitant system, a symmetrical (homogeneous) membrane, a symmetric membrane having separation layers with equal separation characteristics on both of their surfaces, asymmetric membranes having a separating layer on one or both sides or asymmetric membranes without separating layers can be obtained. From the disclosure of Scholander, one cannot say with certainty which type of membrane is produced.

In column 4 methods A and B Scholander refers to membranes made by a phase inversion process, i.e. to a process in which a membrane is precipitated from a casting solution into a coagulation bath. In the introductory part of its specification, Scholander refers to general conditions for preparation of phase inversion membranes. Looking to

column 3, lines 15-29, Scholander describes the preparation of hollow fiber membranes. Beginning at line 22, Scholander explains that in the manufacturing process, the core liquid and coagulation bath contain a non-solvent for the membrane forming polymer and both take part in the coagulation of the spinning solution and formation of the membrane. Thus, in case a separation layer may be produced during the precipitation of the membrane, this separation layer may be 1) on the lumen side, 2) on the outside of the hollow fiber membrane or 3) on both sides.

Looking to lines 30-39 of column 4, Scholander refers to surface modified skinless microporous polyamide membranes, which have been obtained by precipitating the membrane in a coagulation bath. These membranes are skinless, i.e. have no separation layers.

Included with this response is an excerpt from the textbook of M.C. Porter entitled "Handbook of Industrial Membrane Technology". Pages 9-11 reveal explanations regarding the symmetric microporous phase inversion membranes. In the middle of the first full paragraph on page 9, it states that, "[T]his type of membrane can be made from almost any polymer which is soluble in an appropriate solvent and can be precipitated in a non-solvent". Looking now to the last paragraph on page 13 and continuing onto page 14 the handbook refers to the formation mechanism of microporous symmetric or asymmetric membranes, i.e. no general differentiation is made between the formation mechanisms of these types of membranes. On pages 20 and 21 of the handbook, different structures of phase inversion membranes are

presented, amongst others a microfiltration membrane having no skins on the surfaces (photograph (a)) and a symmetric membrane with a dense skin and a uniform pore size distribution (photograph (d)).

Thus, those skilled in the art would disagree with the Examiner's opinion that Scholander implicitly discloses that bringing the first and/or second surface in contact with a precipitant system would inevitably result in the formation of a membrane having a separating layer on the first and/or second surface, simply because said opinion lacks technical basis in Scholander. Applicant must re-emphasize that Scholander neither explicitly nor implicitly discloses a method for the production of integrally asymmetric membranes as claimed in claim 1 of the present invention. Hence, Scholander fails to disclose all of the elements of claim 1. Thus, claim 1 is not anticipated by Scholander and therefore, this rejection must fail.

Inevitably, Scholander neither discloses an integrally asymmetric membrane with at least one separating layer and a supporting layer, which is characterized in that a polyelectrolyte with negative fixed charges, but having no positive fixed charges, is physically bound in the separating layer and is also characterized in that the supporting layer is free from polyelectrolyte. Thus, in contrast to the Examiner's conclusions in items 8, 9 and 10 of the present office action, the integrally asymmetric membrane of claim 12 and its preferred embodiments according to claims 14-16 and 18 are novel over Scholander. Hence, Scholander fails to disclose all of the elements of claim 12.

Thus, claim 12 and its dependent claims are not anticipated by Scholander and therefore, this rejection must fail.

In reference to claims 2-11 and 14-18, "[I]f an independent claim is not anticipated by prior art, then its dependent claims, which necessarily include the limitations of the independent claim, are not anticipated either. *Kovin Assoc. v. Extech/Exterior Technologies*, 2006 U.S. Dist. LEXIS 63250 (N.D. Ill. 2006), citing *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1296 (Fed. Cir. 2002). Thus, claims 2-11 and 14-18 are not anticipated by Scholander and should be allowed.

Moreover, the method of claim 1 and the membrane of claim 12 of the present invention are not obvious under 103(a) over Scholander. The Examiner claims to have established a prima facie case of obviousness against the instant application. MPEP § 2143 "Basic Requirements of a *Prima Facie* Case of Obviousness" states:

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine references teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all claim limitations.

Regarding the third criterion, the court has stated that "to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art." *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Applicant contends that the prior art reference Scholander fails to teach, suggest, or

provides a motivation for an integrally asymmetric membrane as described in the claims of the instant invention.

The instant application is directed to a membrane having improved separation characteristics and to a method for production of such a membrane. Starting from a membrane having an integrally asymmetric structure across its wall thickness and having at least one separating layer and a supporting layer adjoining the separating layer, the improvement is achieved for the membranes of the invention by physically binding a polyelectrolyte with negative fixed charges, but without positive fixed charges, to the separating layer, while leaving the supporting layer free from polyelectrolyte.

Such a membrane can be produced by a method as disclosed in claim 1 of the present invention. The method describes a process for creating an integrally asymmetric membrane with at least one separating layer and a supporting layer adjoining the separating layer, in which process a spinning solution is converted into a shaped object with a first and second surface (i.e. for example a hollow fiber or film) and thereafter the shaped object is brought with its first and/or second surface into contact with a precipitation system, resulting in the formation of a membrane having a separating layer on the first and/or second surface. This means that the precipitation system must be such and must act on the shaped object such that a separating layer is formed on the surface of the shaped object that had been brought into contact with the precipitation system.

As explained above, Scholander does not disclose, either explicitly or implicitly, membranes having a separating layer. Additionally, Scholander does not disclose, either explicitly or implicitly, a method for the production of an integrally asymmetric membrane with a separating layer and a supporting layer. Moreover, Scholander fails to address features such as the separating characteristic of a membrane, let along how to improve that separating characteristic. Instead, Scholander aims at improving the biocompatibility of the membranes (see title or column 3, line 65 to column 4, line 4). Additionally, Scholander teaches away from using negatively charged surfaces as can be seen in column 1, lines 50-54. In fact, even though a polyelectrolyte with negative fixed charges is passively mentioned in column 4, line 59 to column 5, line 2 among numerous other substances for surface modification, Scholander only demonstrates positively charged substances in its examples.

The prior art reference or combination of references relied upon by the Examiner must teach or suggest all of the limitations of the claims. See *In re Zurko*, 111 F.3d 887, 888-89, 42 U.S.P.Q.2d 1467, 1478 (Fed. Cir. 1997); *In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970) ("All words in a claim must be considered in judging the patentability of that claim against the prior art."). The teachings or suggestions, as well as the expectation of success, must come from the prior art, not applicant's disclosure. See *In re Vaeck*, 947 F.2d 488, 493, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). In this instance, from the information detailed above, it is clear that Scholander fails to teach or suggest all the limitations of Applicant's claims. Accordingly, Scholander does not disclose all of the elements of claims 1 and 12 and

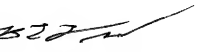
therefore, this rejection must fail. Thus, claims 1 and 12 are not obvious over Scholander and should be allowed.

In reference to claims 2-11 and 14-18, dependent claims are nonobvious under section 103 if the independent claims from which they depend are nonobvious. *Hartness Int'l, Inc. v. Simplimatic Eng'g Co., 819 F.2d 1100, 1108, 2 USPQ2d 1826, 1831 (Fed. Cir. 1987); In re Abele, 684 F.2d 902, 910, 214 USPQ 682, 689 (CCPA 1982); see also In re Semaker, 702 F.2d 989, 991, 217 USPQ 1, 3 (Fed. Cir. 1983).* Thus, claims 2-11 and 14-18 are not obvious over Scholander and should be allowed.

Conclusion

In view of the foregoing, Applicant respectfully requests an early Notice of Allowance in this application.

Respectfully submitted,



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